

specification at, for example, page 14, lines 5-9. Claims 2-11 have been amended to correct minor grammatical informalities. Independent claims 1 and 13 have been amended to recite that the composition is effective to form a film encapsulated liquid *in situ*. Support for this recitation can be found in the original specification at, for example, page 13, lines 25-26. Accordingly, the changes are not new matter.

#### I. The Information Disclosure Statement:

The Examiner has pointed out that certain publications were not provided in the Information Disclosure Statement (IDS) filed July 12, 1999. It appears that the documents EP 0179022, EP 0508699, EP 0846686, EP 0295117, EP 0892060, EP 0007812, EP 0002916, and WO 96/29073 were inadvertently separated from the IDS package. Accordingly, Applicants enclose herewith the documents listed above. Any fees required with this transmittal should be charged to Deposit Account 13-2755.

#### II. Rejections under 35 U.S.C. §112

Claims 1-3, 5, 6, and 11-13 have been rejected as allegedly being unclear whether the percentages recited in each are based on weight or volume. The claims have been amended to recite the percentage ranges as w/v as stated in the original specification at, for example, page 14, lines 5-9. Applicants respectfully submit that one of ordinary skill recognizes that term to represent percentages calculated from the units g/mL. For example, U.S. Patent No. 5,780,044 describes a typical w/v usage at column 12, lines 36-38.

Accordingly, applicants respectfully submit that the rejections under 35 U.S.C. §112 have been overcome and request withdrawal of the rejections.

#### III. Rejections under 35 U.S.C. § 102:

Claims 1-6, 8-11, and 13 have been rejected as allegedly anticipated by US Patent No. 5,278,202 ("Dunn"). The claims have been amended to overcome the rejection.

Applicants respectfully submit that Dunn does not disclose a composition effective to form a film encapsulated liquid *in situ* as claimed in independent claims 1 and 13, as amended. Instead, Dunn forms a solid, as stated at column 4, line 40. Dunn repeatedly refers to the Dunn composition forming a solid. For example, Dunn states at column 6, lines 14-16, that "[o]nce in place, the solvent dissipates, the remaining polymer solidifies, and a solid structure is formed";

and at column 7, line 18, (referring to the injectable implant) as being an “in-situ, solid forming implant.”

Further, Dunn states at column 5, lines 12-13, (emphasis added) that the solvents should “allow water to permeate into the polymer solution and cause it to coagulate or solidify” and at column 7, line 29, describes “the solid implant formed within the injectable polymer solution.” Thus, Dunn discloses a composition that forms a solid, not a film encapsulated liquid *in situ* as claimed in independent claims 1 and 13, as amended.

Claims 1-14 have been rejected as allegedly anticipated by US Patent Nos. 5,780,044 (“Yewey”) and 5,733,566 (“Lewis”). The claims have been amended to overcome the rejection.

Applicants respectfully submit that neither Yewey nor Lewis discloses the present invention as claimed in independent claims 1 and 13, as amended. Yewey describes compositions that, after being inserted, “solidify or cure . . . to form a solid or gelatinous matrix,” (Col. 5, lines 7-9). Similarly, Lewis forms microparticles that serve as a matrix from which the active agent is dispersed. Thus, neither discloses a composition that forms a film encapsulated liquid *in situ* as claimed in independent claims 1 and 13, as amended.

Accordingly, independent claims 1 and 13, as amended, are not anticipated by Dunn, Yewey, or Lewis. Claims 2-12 and 14, depending from claims 1 and 13 respectively, are also not anticipated by Dunn, Yewey, or Lewis for that reason as well as for the additional elements they recite. Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 102.

#### IV. Rejections Under 35 U.S.C. § 103:

Claims 1-14 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Dunn, Yewey, or Lewis. Applicants respectfully submit that none of the references make obvious the present invention as claimed in claim 1 or 15, as amended.

As described above, none of the references discloses a composition that forms a film encapsulated liquid *in situ* as claimed in independent claims 1 and 13, as amended. Furthermore, each reference teaches away from the present invention. Dunn states at column 7, line 29, that “the solid implant [is] formed within the injectable polymer solution.” Thus, Dunn teaches away from forming a film *in situ* encapsulating a liquid. Yewey and Lewis each describes solidifying compositions to form a matrix of solid microparticles from which the active ingredient is dispersed. Thus, they teach that the active ingredients should be incased within a multitude of solid microparticles that, in combination, form a matrix – opposite in scale, number, and form

from the film encapsulated liquid formed *in situ* as claimed in independent claims 1 and 13, as amended. The scale of the Yewey and Lewis microparticles are much smaller, the number much more numerous, and the solid matrix form is different from the film encapsulated liquid. One of ordinary skill reading Dunn, Yewey, or Lewis is given no disclosure, teaching, or suggestion of the composition of the present invention which forms a film encapsulated liquid *in situ*.

Therefore, independent claims 1 and 13 are not obvious in light of Dunn, Yewey, or Lewis. Claims 2-12, and 14 depending from claims 1 and 13 respectively are also not obvious for that reason as well as for the additional elements they contain. Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103.

#### Conclusion

Applicants respectfully submit that the application is in condition for allowance because all the rejections have been overcome and request a Notice to that effect.

If a telephonic discussion would be helpful to further the prosecution, Applicants' attorney can be reached at the telephone number below. Correspondence should continue to be directed to the address below. Any deficiencies in fees should be charged to Deposit Account 13-2755.

Respectfully submitted,

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